

## REMARKS

By this Amendment, claims 1, 4, 6, 10, and 15-22 have been amended, claims 2, 3, 7-9, 11-14, having previously been canceled. Accordingly, claims 1, 4-6, 10 and 15-22 are pending in the application. No new matter has been added.

Applicants thank the Examiner for the clear indication of the rejections that have been overcome or rendered moot by amendments and/or arguments in the amendment filed 19 June 2008.

### *Claim Rejections – 35 U.S.C. 112, second paragraph*

The Examiner maintained the rejection of claim 10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that no remarks in the amendment filed 19 June 2008 were directed to claim 10. The Examiner finds “and/or” to render the claim indefinite.

The Examiner will note that claim 10 has been amended to delete “and/or.” Additionally, claims 17 and 21 have been similarly amended to remove the offending language, and claims 15, 16, and 18 -22 have been amended to correct related and other indefiniteness issues not pointed out by the Examiner, though only claim 10 was rejected hereunder. It is thus believed that the rejection of claim 10 has been overcome.

### *Claim Rejections – 35 U.S.C. 103(a)- Nagashima*

Claims 1, 4-6, 10 and 15-22 are rejected as obvious, under 35 U.S.C. 103(a) in view of Nagashima, et al., U.S. 6,269,817, (“Nagashima”). The Examiner contends that Nagashima discloses all limitations of the rejected claims except (1) the volumetric limitations of the article and (2) the use of water in steps (a) and (b) of claim 1. The Examiner concludes that it would have been obvious to prepare a protein-free composition comprising a scaffold-forming agent, squalene and other cosmetic substances in the presence of water, and apply the composition to the skin of a human or animal. The Examiner lends no patentable weight to the limitations “molded” or “freeze-dried.”

The Examiner concludes that because the dimensional parameters of the claimed shaped articles (volume and diameter) are result effective variables, they are subject to optimization by

the skilled artisan via routine experimentation. Hence, the claimed subject matter is obvious in light of Nagashima. Applicants respectfully traverse the rejection.

The claimed invention is not obvious for at least two reasons: (1) Nagashima expresses a criticality of particle size of less than 1 millimeter. (2) The volume of the claimed shaped article is, at a minimum some 200 times greater than the maximum volume of a particle as disclosed by Nagashima.

Upon study of Nagashima, the skilled artisan would not be motivated, by a desire for optimization or otherwise, to use a particle greater than 1 millimeter (i.e. 1000 microns) in diameter. As noted at col. 8, lines 27-29, “[t]he particle size of the disintegrating granules thus formed is preferably 100 to 1000  $\mu\text{m}$ , and even more preferably 200 to 600  $\mu\text{m}$ . A particle size of less than 100  $\mu\text{m}$  results in poor massaging effects, and fails to provide the pronounced effects in improving skin color or the effects in promoting blood circulation associated with the massage. A particle size of more than 1000  $\mu\text{m}$  results in rough feeling and in initial stimulation too intense when rubbed into the skin.” Nagashima provides concrete reasons why particle sizes outside the range of 100 to 1000 microns are undesirable.

There is therefore no motivation, absent Applicants’ disclosure, to use a particle having a diameter greater than 1 millimeter. In fact, the skilled artisan would be discouraged from the same based on Nagashima’s teachings.

Even assuming *arguendo* that the skilled artisan was motivated to do some amount of routine experimentation with the particle sizes of Nagashima to optimize some property or behavior of such particles, he would not be motivated to increase the particle size by a factor of, at a minimum, a factor of at least 200, in terms of volume. Presuming a spherical disintegrating particle having the maximum diameter of 1 millimeter as disclosed in Nagashima, this results in a maximum particle volume of  $0.52 \text{ mm}^3$  or  $0.00052 \text{ cm}^3$ . This is 0.52% of the minimum instantly claimed particle volume ( $0.1 \text{ cm}^3$  or  $100 \text{ mm}^3$ ). If the maximum instantly claimed particle volume ( $6 \text{ cm}^3$  or  $6000 \text{ mm}^3$ ) is compared to the maximum particle volume obtainable from Nagashima, the ratio is  $6000 \div 0.52$  or about 11500 to 1.

Clearly, no one would be motivated to adjust the particle volumes of Nagashima’s disintegratable particles by a factor of 200 to 11500 times given the strong teaching away from using any particle larger than 1 millimeter, given that volume depends on diameter.

Further, with respect to both the diameter and volume of Nagashima's particles, Nagashima teaches that its particles are discharged from a container in constant amounts, taking the forms of crèmes, gels, pastes and emulsions, paragraph bridging cols. 12-13. The particles must be small enough to discharge from a such a container without clogging, such as pump containers and metering containers. The skilled artisan will immediately recognize that such containers also include atomizers and aerosol spray cans. It is unlikely that the instantly claimed particles, having a minimum diameter of 3 mm, could be discharged from a container as envisioned by Nagashima.

Additionally, Nagashima discloses the use of a variety of additives, at least some of which would fall under the moniker "protein-based," and hence outside the scope of the instant claims. Most pointedly, in Test Example 1, Table I, column 16, the "massaging cosmetic" of Nagashima includes L-arginine, an amino acid, which is a protein building block. Nagashima discloses the use of "softeners includ[ing] [ ] lysine, arginine, histidine, ornithine, canavanine and other basic amino acids, [ ] urea, 2-hydroxyguanidine, 2-(2-hydroxyethoxy)ethylguanidine and other such amines, as well as the peptides noted in Japanese Laid-Open Patent Applications 62-99315 and 2-178207," col. 13, lines 23-34. Further, Nagashima discloses the use of "corneal layer protectants include[ing] hyaluronic acid, chondroitin sulfate and other such mucopolysaccharides, gelatin, collagen and other such proteins," col. 13, lines 49-53.

Further, Nagashima discloses that "[a] blood circulation promoter **should** be included to obtain greater skin color improving effects with the massage. [ ] Examples of vegetable extracts include those disclosed as having blood circulation promoting effects [ ] such as extracts of arnica, crataegus, cinchona bark, Salvia officinalis, Tilia miqueliana, Panax ginseng, juniper, rosemary, Hypericum erectum, gingko, melissa, Ononis spinosa, marronnier, swertia herb, garlic, camomile, thyme, field mint, nettle, cayenne, ginger, hops, common horsechestnut, lavender, carrots, mustard, cinnamon, pine, cnidium rhizome, elderberry, mountain dropwort, Scopolia japonica, peony, wax myrtle, Saururaceae, nupharis rhizoma, persimmon, marigold, corn poppy, gentian, grapes, glehnia root, orange, Chinese lemon, calamus, Japanese summer orange, witch-hazel, yellow sweetclover, common fennel, prickly mountain ash, peony root, eucalyptus, mugwort, Isodon japonicus, rice, Sophora flavescens, ginger and clove," col. 9, lines 37-64, emphasis supplied. Clearly, at least some of these vegetable extracts will contain proteins.

While Applicants do not contend that every embodiment of Nagashima includes a protein, it cannot be disputed that there is much disclosure of useful and desired ingredients therein that include a protein, militating against a finding of obviousness of the instantly claimed invention.

Based on all of the foregoing, Applicants respectfully request that Examiner withdraw the obviousness rejection over Nagashima.

*Specification*

The Examiner objects to the specification as failing to provide antecedent basis for the subject matter of the claims. The Examiner cannot find “scaffold-forming agent,” however essentially believes that “skeleton-forming agent,” which is present in the specification, means the same.

The Examiner will note that all affected claims have been amended to replace “scaffold-forming agent” with “skeleton-forming agent.” It is this believed the objection is rendered moot.

Application No. 10/531,346  
Amendment dated: 5 February 2009  
Reply to Office action of: 6 November 2008

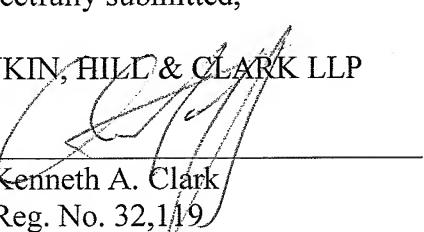
***Conclusion***

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to Deposit Account No. 18-0160, Order No. GIL-16027.

Respectfully submitted,

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